chapter, preparing the sample for assay as follows: Dissolve an accurately measured representative volume of the sample in sufficient absolute methyl alcohol to give a solution of convenient concentration. Immediately further dilute with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, using a representative aliquot of the drug prepared for assay as described in paragraph (b)(2) of that section.

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted sample.

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§ 440.155d Penicillin G benzathine tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin G benzathine tablets contain penicillin G benzathine with one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. Each tablet contains penicillin G benzathine equivalent to 200,000 units of penicillin G. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of penicillin G that it is represented to contain. Its moisture content is not more than 8.0 percent. The tablets shall disintegrate within 1 hour. The penicillin G benzathine used conforms to the standards prescribed by § 440.55a(a)(1), except sterility and pyrogens.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin G benzathine used in making the batch for potency, moisture, pH, penicillin G content, and crystallinity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) The penicillin G benzathine used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay*—(1) *Potency.* Using the penicillin G working standard as the standard of comparison, assay for potency by either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar containing 200 milliliters of absolute methyl alcohol. Blend for 1 minute. Add an additional 300 milliliters of absolute methyl alcohol and blend again for 2 to 3 minutes. Immediately further dilute an aliquot with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Weigh and finely powder six tablets. Transfer two accurately weighed portions of the tablets, each equivalent to 200,000 units of penicillin G, to two separate 100-milliliter volumetric flasks. Dilute one flask, which is to be used as the blank, to volume with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), and proceed as directed in § 436.204(d) of this chapter. In lieu of directions in § 436.204(e) (1), (2), and (3), to the other flask add 10 milliliters of 1.0*N* NaOH and mix well. Allow to stand for 15 minutes, then add 10 milliliters of 1.2*N* HC1, and dilute to volume with distilled water. Pipette a 2.0-milliliter aliquot into a 125-milliliter glass-stoppered Erlenmeyer flask and proceed as directed in § 436.204(c)(4) of this chapter.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter.

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